IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RELYPSA, INC. and VIFOR (INTERNATIONAL) LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-106 (MN)
ALKEM LABORATORIES LTD. and ASCENT PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 20th day of July 2021:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 8,147,873 ("the '873 Patent"), 8,337,824 ("the '824 Patent"), 9,492,476 ("the '476 Patent") and 9,925,212 ("the '212 Patent") with agreed-upon constructions are construed as follows (*see* D.I. 70 at 1-2):

1. "cation exchange, crosslinked . . . polymer or a salt thereof" means "crosslinked polymer or a salt thereof that is able to exchange cations" ('873 Patent, claim 1)

2. "cation exchange polymer salt" means "polymer salt that is able to exchange cations" ('824 Patent, claims 1-2, 7-8, 52, 60-61 & 69)

3. "cation exchange polymer" means "polymer or salt thereof that is able to exchange cations" ('476 Patent, claim 1; '212 Patent, claim 1)

Further, as announced at the hearing on July 8, 2021, IT IS HEREBY ORDERED that the disputed claim term of the '873 Patent is construed as follows:

1. "wherein the alpha-fluoroacrylic acid polymer is crosslinked with divinylbenzene" shall be given its plain and ordinary meaning, which requires divinylbenzene to be a crosslinking agent but does not exclude other additional crosslinking agents ('873 Patent, claim 1)

The parties briefed the issues (*see* D.I. 79) and submitted an appendix containing intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 80), and Plaintiffs Relypsa, Inc. and

Vifor (International) Ltd. provided a tutorial describing the relevant technology (D.I. 84).[1] The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim term, heard oral argument (*see* D.I. 89) and applied the following legal standards in reaching its decision:

I. LEGAL STANDARDS

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of

[1] Defendants Alkem Laboratories Ltd. and Ascent Pharmaceuticals, Inc. did not submit a tutorial.

the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer

from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

II. THE COURT'S RULING

The Court's ruling regarding the disputed claim term of '873 Patent was announced from the bench at the conclusion of the hearing as follows:

> . . . At issue in this case we have four patents, but only one term in one of those patents, U.S. Patent No. 8,147,873, is disputed.
>
> I am prepared to rule on this dispute. I will not be issuing a written opinion, but I will issue an order stating my ruling. I want to emphasize before I announce my decision that although I am not issuing a written opinion, we have followed a full and thorough process before making the decision I am about to state. I have reviewed the '873 Patent and the excerpts of the '873 Patent prosecution history submitted as well as the expert declarations and other materials submitted in the joint appendix. Plaintiffs submitted a tutorial on the technology. There was full briefing on the disputed term and there has been argument here today. All of that has been carefully considered.[2]
>
> As to my rulings. I am not going to read into the record my understanding of claim construction law generally. I have a legal standard section that I have included in earlier opinions. I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.
>
> Now the disputed term, which is "wherein the alpha-fluoroacrylic acid polymer is crosslinked with divinylbenzene" in claim 1 of the '873 Patent. Plaintiffs propose that no construction is necessary. Defendants propose "wherein divinylbenzene is the only

[2] The parties did not raise any disputes as to the person of ordinary skill in the art ("POSA") that are relevant to the issues raised in connection with claim construction.

crosslinking agent that links polymer chains of alpha-fluoroacrylic acid to one another."

The crux of the dispute is whether the term is limited to a polymer that is crosslinked with only divinylbenzene and no other crosslinking agent. Here, I agree with Plaintiffs that the term requires that divinylbenzene be a crosslinking agent, but it need not be the only crosslinking agent.

This construction is supported by the ordinary meaning of the claim language itself, which requires that the alpha-fluoroacrylic acid polymer is crosslinked with divinylbenzene but does not state that the polymer is only crosslinked with divinylbenzene. And in the context of the claim, I do not read the word "is" to convey exclusivity such that the only crosslinking agent permitted is divinylbenzene.[3] And there is nothing in the specification that contradicts this meaning as it neither requires nor excludes the use of any one or more crosslinking agents.[4]

Nor do I find that the prosecution history requires the claims to be limited to having divinylbenzene as the only crosslinker – either through repeated statements about the invention as *Phillips* counsels or as a clear and unmistakable disclaimer.

As originally filed, claim 1 did not require a crosslinking agent, but some of the dependent claims did and some of those required divinylbenzene as the crosslinking agent. After an initial rejection, the applicants amended claim 1 to add the language "a cation exchange" to the crosslinked alpha-fluoroacrylic acid polymer, but the applicants did not change the dependent claims.[5] In response to the rejections, the applicants noted that certain dependent claims [*i.e.*, then-pending claims 2, 5, 7, 9, 10, 12 and 15] "require divinylbenzene as the crosslinking agent."[6] Applicants made similar statements in response to further rejections and also explained that the claims were not obvious over the prior art cited

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3 *See, e.g.*, *Entegris, Inc. v. Pall Corp.*, No. 06-10601-GAO, 2008 WL 886034, at *5 (D. Mass. Mar. 31, 2008) (noting that the word "is" does not necessarily indicate exclusivity and that the context of surrounding claim language must be considered).

4 Indeed, the parties largely ignore the specification in their arguments. Plaintiffs, however, do point out that the specification provides that "crosslinking agents" plural may be used to prepare ion exchange polymers. (*See* '873 Patent at 14:2-11).

5 (D.I. 80 at JA0173-74).

6 (*Id.* at JA0180).

because it would not have been obvious from the references cited by the Examiner to use divinylbenzene as "the" crosslinking agent claimed.[7]

Applicants also made additional amendments to claims and cancelled certain claims, ultimately ending up with claim 1 containing the disputed language "alpha-fluoroacrylic acid polymer is crosslinked with divinylbenzene."[8] None of the amendments or statements made, however, require divergence from the plain and ordinary meaning or evidence a clear and unmistakable disclaimer of claim scope that allows more than one type of crosslinking agent. The statements made during the prosecution history appear to explain the scientific reasons why prior art cited by the Examiner did not render the claims obvious.

And although some of those statements referred to divinylbenzene as "the" crosslinking agent, I do not see that as requiring only divinylbenzene and excluding other additional crosslinking agents. Indeed, those statements can readily be interpreted as distinguishing the claims based on the presence of divinylbenzene as a crosslinking agent rather than it being the only crosslinking agent. And there is no reference anywhere to anything that would exclude other crosslinking agents as long as divinylbenzene is also used.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

7 (*Id.* at JA0199-200).

8 (*See, e.g.*, *id.* at JA0208-09, JA0212, JA0230, JA0234-35 & JA0238).